**Liberate From Sugar, Mate!**

## PARTICIPANT INFORMATION SHEET

**Researcher Introduction**

We are student dietitians completing Master’s of Nutrition & Dietetics. Our supervisors and collaborators work in the areas of sport and exercise science, health science, nutrition and food technology at Massey University.

**Invitation to Participate in Research Study**

If you identify as having a “sweet tooth”, we would like to invite you to take part in our study. Gymnema sylvestre (GS) is a plant that contains ingredients that prevent sugar from activating sweet receptors on the tongue. This results in a reversible reduction in perception of sweet flavours for 30 – 60 minutes. Several GS-containing mints have been developed to reduce cravings for sugar-sweetened food products. You will need to be available to take part in **three separate** **interventions** during the course of the study (each 14 days long) which includes **four visits** to the Massey University Albany Campus.

**Participant Recruitment**

Healthy men and women (aged 18-60 years) without diagnosed medical conditions including (but not limited to) diabetes, heart disease or cancer; not currently smoking; and not currently taking medications that affect taste and smell, are invited to participate in this study. Participants will undertake a general health screening questionnaire to ascertain whether they are able to be recruited into the study.

**The four visits will each be of approximately 45 - 60 minutes duration**. There will also be the (optional) opportunity for 10 participants to be interviewed as part of this study, which will increase the visit time by **30 minutes**.

**Project Procedures and Participant Involvement**

If you agree to participate, you will be asked to participate in **three 14-day experiments** that are designed to assess the effects of several GS-containing mint products on 1) motivations to consume sugar-sweetened food, 2) cravings for sugar-sweetened food and 3) total intake of sugar-sweetened food. In each 14-day trial you will be asked to undertake the following:

Take allocated mint orally three times per day at specified time points: between breakfast and lunch, between lunch and dinner, after dinner but before bed OR to take the allocated mint orally as many times as you like / need throughout the day (up to six mints per day) at times that suit you. The specific procedure will be explained to you prior to each trial. You will also need to complete a Compliance Diary each day during each of these 14-day interventions: the Compliance Diary will help researchers be able to see what time and the reason why you took the GS-containing mint, or alternatively any reason why the GS-containing mint was not taken (for example, you forgot to take the mint).

Possible side effects: Similar GS-containing mints have been used in many other studies and side effects are rare. Those that have experienced any reported mild gastrointestinal upset. Taste effects rarely last longer than 30 - 60 minutes. If you experience any persisting side effects during the study, we encourage you to get in contact with a member of our research team and your health professional.

For **all four visits**, you will be asked to complete the following:

* A food frequency questionnaire: specifically developed for assessing sweet food consumption as well as related behaviours.
* A beverage questionnaire
* A food cravings questionnaire
* Bioelectrical Impedance Analysis (BIA)
  + A machine that assesses your body composition. The machine passes a small electrical current through your body. The conductivity of this current is higher through muscle and bone, and lower through fat mass.
  + You will be required to not eat for two hours before your scan.
  + The researchers will sanitise the machine before you use it, which will involve stepping onto the BIA machine with bare feet.
  + Your height (which will be take prior to stepping onto the BIA machine), age, gender and weight (which is measured by the BIA machine) will be entered into the machine by the researcher, and then you will hold onto two handles on either side of the machine and the analysis will begin. The machine will print out the results of the analysis, which the researchers will keep securely and allow you to see **after the research project has finished** if you wish**.**
  + **Risks:** The BIA does not involve exposure to radiation and is considered safe for most people to use. All body measurements will be taken in a private room for your comfort, and you are encouraged to discuss any feelings of discomfort with the researchers, your health professionals, or to contact any of the numbers listed below (Samaritans or Lifeline) if you experience psychological distress related to the body measurements.

For the **first three visits** you will also be asked to complete sensory testing with the different kinds of GS mints you will be taking for the three 14-day interventions. This will involve the following:

1. Record your hunger and desire for sugar-sweetened food
2. Consume a serving of confectionary
3. Record how pleasant you found the confectionary AND your desire for a second serving
4. You will be given a mint and instructed on how to take it orally
5. AGAIN record your desire for a second serving of confectionary
6. Consume a second serving of confectionary
7. Record how pleasant you found the second serving of confectionary AND your desire for a third serving
8. From this point, any further servings of confectionary are optional (with steps 5 to 7 being repeated in between consumptions). You can at any point decide you would not like another serving of confectionary, at which point sensory testing will stop.

Interviews: We will ask 10 participants to volunteer for interviews, **which will be taken at each of the four visits to campus**. The **same people** will be interviewed at each visit. We will ask questions related to nutrition, behaviour and sensory aspects related to sugar-sweetened food. Sessions will be audio-recorded. You will be asked to sign a separate consent form if you wish to be involved in the interviews and consent to having your answers recorded.

After each visit to the Massey University Albany Campus you will receive $20 koha.

**Participant’s Rights**

You are under no obligation to accept this invitation. Should you choose to participate, you have the right to:

* Decline to answer any particular question
* Withdraw from the study at any time, even after signing a consent form (if you choose to withdraw you cannot withdraw your data from the analysis after the data collection has been completed)
* Ask any questions about the study at any time during participation
* Provide information on the understanding that your name will not be used unless you give permission to the researcher
* Be given access to a summary of the project findings when it is concluded

**Good Practice and Cultural Safety for Massey University Research**

We have considered the inclusion of Māori and indigenous values and concepts, allowing for the use of whānau support and appropriate Māori protocols. We acknowledge the concept of manaakitanga, respecting the participants’ inherent dignity and acting in a caring manner towards them by way of:

* Taking full responsibility to perform research in a safe and ethical manner (aroha)
* Providing the participant with all of the critical information regarding the study in a clear way, so they can make informed decisions (tūmanako and whakapono)
* An awareness of the cultural significance and sensitivity for a culturally safe implementation of the study (māhaki)
* Respect for the privacy and confidentiality of Māori participants

**Confidentiality**

All data collected will be used solely for research purposes and has the possibility of being presented in an international journal. All personal information will be kept confidential by assigning numbers to each participant. No names will be visible on any papers on which you provide information. All data / information will be dealt with confidentiality and will be stored in a secure location for five years on the Massey University Albany Campus. After this time, it will be disposed of by an appropriate staff member from the School of Sport, Exercise and Nutrition.

**Project Contacts**

If you have any questions regarding this study, please do not hesitate to contact any of the following people for assistance:

Mr David Hsiao (student dietitian)

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**Additional Contacts / Useful Links**

If you have any concerns about your diet and / or your health during the project, or any allergic reactions to the products providedplease contact your GP. You may also find the following contact information useful:

* Samaritans – 0800 726 666
* Lifeline NZ – 0800 543 354

**Committee Approval Statement**

This project has been reviewed and approved by the Massey University Human Ethics Committee: Southern A, Application 22/21. If you have any concerns about the conduct of this research, please contact Dr Negar Partow, Chair, Massey University Human Ethics Committee: Southern A, telephone 04 801 5799 x 63363, email humanethicsoutha@massey.ac.nz.